

K013912 CREATINE KINASE (CK-NAC)Jan 18, 2002
52 days to decisionK013912 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k013912/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS) |
| Date received | Nov 27, 2001 |
| Decision date | Jan 18, 2002 |
| Days to decision | 52 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Jas Diagnostics, Inc. |
| Location | Miami, FL, US |
| Contact | David Johnston |
| 510(k) history | 20 submissions · 20 cleared · 2000-2014 |

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